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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/485,131	ROHDE ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 16-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 16-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This action is in response to the Reply filed March 12, 2003, and the Reply filed November 22, 2002. Claims 1-11 have been amended, claims 12-15 have been canceled, and claims 16-22 have been added. Claims 1-11 and 16-22 are now pending and under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

3. Claims 1-11 and 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11 and 16-22 are indefinite over the recitation of the phrase "determining the degree of genetic relatedness between the DNA sequences." It is unclear as to what actual method steps might be encompassed by this language, and further as to how this recitation relates to or results in DNA-fingerprint analysis, as required by the claim preamble. Clarification is required.

Claims 2 and 18-22 are indefinite over the recitation of the limitation "the DNAs sequences" in claim 2, because there is insufficient antecedent basis for

this limitation. It is noted that claims 18-22 also recite the language "the DNAs sequences," and may require amendment to provide proper antecedent basis upon the amendment of claim 2.

Claims 3-6 are indefinite over the recitation of the limitation "the DNAs to be analyzed are separated on a gel" in claim 3. First, there is insufficient antecedent basis for the limitation "the DNAs to be analyzed." Second, it is unclear as to whether this recitation is intended to further limit the previously recited "separating" step, or whether the claims are drawn to an additional step requiring gel analysis of "DNAs to be analyzed." It is further noted that while claim 3 currently provides antecedent basis for the recitation "the DNAs," an amendment of the language "the DNAs to be analyzed" in claim 3 may also require an amendment of claim 5 such that antecedent basis is provided for all terms.

Claims 5-6 are indefinite over the recitation of the limitation "performing a Southern blot and transferring the DNAs onto a membrane" in claim 5. It is noted that a step of "performing a Southern blot" inherently requires transferring of nucleic acids to a membrane. Accordingly, it is unclear as to whether the claims are intended to require multiple steps of transferring, or whether a portion of the claim is intended to provide a further description of Southern blotting. Clarification is required.

Claims 5-6 are indefinite over the recitation of the phrase "whereby hybridization can be visualized with a probe" in claim 5. It is unclear as to whether this language requires hybridization and visualization, or whether this

phrase merely describes properties of the recited "membrane." Clarification is required.

Claim 6 is indefinite over the recitation of the limitation "wherein the probe is the primer or the primer pair hybridizes to said DNA sequences." First, it is unclear as to whether this recitation requires that either the "primer or the primer pair" may be "the probe," or whether "the probe is the primer" and "the primer pair hybridizes to said DNA sequences." Further, it is unclear as to how the recitation "hybridizes to said DNA sequences" further limits the claim (e.g., does this recitation refer to a property of the primer pair or of the primer or the primer pair, or does this language require hybridization?). Clarification is required.

Claim 9 is indefinite over the recitation of the limitation "wherein the primer or primer pair corresponds to any one of the sequences…" It is unclear as to whether this language requires that the "primer pair" must "correspond to" a single one of the recited SEQ ID Nos, or whether Applicant's intent was to require a primer pair in which each primer "corresponds to" one of the SEQ ID Nos. Further, the term "corresponds" is vague and indefinite, as it does not clearly apprise one of skill in the art as to the relationship between the "primer or primer pair" and the recited SEQ ID Nos. For example, does this language require that the primer or primer pair consist of or comprise a recited SEQ ID NO, or would a lesser degree of homology be considered a "correspondence?" Clarification is required.

Claim 16 is indefinite because it is unclear as to how or whether the claim further limits claim 8 to the extent that claim 8 is drawn to something other than a

"non-radioactive label." It is noted that neither claim 8 nor claim 16 actually requires a non-radioactive label. This rejection could be overcome by amending claim 16 to recite "The method according to claim 8, wherein the label is a non-radioactive label, and wherein the non-radioactive label is digoxigenin."

Claim 17 is indefinite because it is unclear as to how or whether the claim further limits claim 8 to the extent that claim 8 is drawn to something other than a "radioactive label." It is noted that neither claim 8 nor claim 17 actually requires a radioactive label. This rejection could be overcome by amending claim 17 to recite "The method according to claim 8, wherein the label is a radioactive label, and wherein the radioactive label is ^{32}P."

Claim Rejections - 35 USC § 102

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS. It is noted that Applicant has amended claims 1-11 such that the claims are now drawn to a method (rather than a use). Claims 16-22 are newly added dependent claims.

4. Claims 1-4, 7-11, 16, and 19-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rohde (Journal of Genetics & Breeding 50:249-261 [9/1996]).

Rohde teaches a method of DNA fingerprinting analysis termed inverse sequence-tagged repeat (ISTR) analysis (p. 250). In ISTR analysis, primers "derived from coconut *copia*-like sequences amplify homo- and polymorphic DNA segments in the analysis of plant, animal and human genomes" (p. 250). Rohde discloses steps of isolating DNA, subjecting isolated DNA to PCR amplification,

separation of PCR products on gels, and analysis of data to compare genotypes (see p. 250). With respect to claims 3-4, Rohde's fingerprinting method comprises separation of PCR products according to length on sequencing gels (page 250; Figs. 2-4, 6-8). Regarding claims 7-8 and 16, Rohde discloses the use of digoxigenin labeled primers and radioactive primers (p. 250). With respect to claims 9-10, Rohde teaches "coconut *copia* sequence-derived" PCR primers ISTR-F1, ISTR-F2, ISTR-F3, ISTR-F5, ISTR-F6, ISTR-F7, ISTR-B1, ISTR-B2, ISTR-B3, ISTR-B4, and ISTR-B5 (Figure 1), corresponding to several of the primers of SEQ ID NOS 4-45 (see p. 15 of the specification, as well as Figure 2), and comprising sequences that "overlap" SEQ ID Nos 4-45. With respect to claim 11, it is an inherent property of Rohde's analyses that they constitute studies of, e.g., biodiversity and genetic relationships. Regarding claims 19 and 22, Rohde discloses the fingerprinting of plants of both *Dicotyledonae* and *Monocotyledonae* (see entire reference, particularly Figures 2, 3, 4, 6). With respect to claim 20, Rohde discloses the fingerprinting of fungi (see, e.g., Figure 2). Regarding claim 21, Rohde discloses the fingerprinting of both human and bovine DNA (see, e.g., Figure 8).

Regarding the rejection of claims 1-11 under 35 U.S.C. 102(b) as being clearly anticipated by Rohde in the Office action of May 22, 2002, the Reply traverses the rejection on the following grounds. Applicant argues that the Rohde reference does not qualify as prior art under 35 U.S.C. 102(b). The Reply states that the instant application is "entitled to a priority date of August 6, 1997," and that the Rohde reference was not printed until April 1997 (as evidenced by

Applicant's "Exhibit 3"), and was not available to the public until September 1998 (as evidenced by Applicant's "Exhibit 1").

These arguments have been thoroughly considered but are not persuasive. First, with regard to the availability of the Rohde reference, the Journal containing the reference was received by the USPTO library on May 12, 1997 (see copy of date stamped cover page attached hereto). While Applicant's "Exhibit 1" appears to show a contents page for Volume 50, Number 3 of the Journal of Genetics & Breeding having a printed publication date of "September 1998," the examiner has inspected an actual copy of that Journal issue, which clearly reads "September 1996" (please see legible copy of that contents page, also attached hereto). Accordingly, while it is acknowledged that it appears the Rohde reference was not available in September 1996, the reference clearly was available in May 1997. Second, it is noted that the instant application was filed August 5, 1998; accordingly, Rohde, even with an availability date of May 1997, qualifies as 102(b) art. While the application does claim foreign priority to August 6, 1997, Applicant is referred to *MPEP* 201.13, which states in part:

> The right to rely on the foreign filing extends to overcoming the effects of intervening references or uses, but there are certain restrictions. For example, the 1 year bar of 35 U.S.C. 102(b) dates from the U.S. filing date and not from the foreign filing date...

While Applicant's foreign priority document might be sufficient to overcome an intervening reference (i.e., a reference filed between the filing of the foreign priority document and of the International application of which the instant application is a 371), the Rohde reference was published prior to Applicant's

foreign priority date, and is not an intervening reference. Accordingly, Rohde qualifies as 102(b) art, and Applicant's arguments are not persuasive.

5. Claims 1-4, 10-11, 18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Welsh et al (Nucleic Acids Res. 18(24):7213-7218 [12/1990]).

Welsh et al disclose a method of DNA fingerprint analysis in which genomic DNA is PCR amplified using arbitrary primers (see entire reference). It is an inherent property of the arbitrary primers of Welsh et al that they would hybridize to the DNA sequences of the claims under sufficiently permissive conditions. Welsh et al discloses steps of isolating DNA (p. 7213), subjecting isolated DNA to PCR amplification (p. 7214), separation of PCR products on gels (Figures 2-5), and analysis of data to compare genotypes (see p. 7215-7218). Accordingly, Welsh et al anticipate the instant claims. With further respect to claims 3-4, it is noted that Welsh et al's fingerprinting method results in the production of multiple PCR products that are separated according to length and displayed on sequencing gels (see, e.g., Figs. 2-5). With respect to claim 10, it is an inherent property of the primers taught by Welsh et al that they overlap the sequences of the claims. With respect to claim 11, Welsh et al's analyses constitute studies of, e.g., biodiversity and genetic relationships. Regarding claim 18 and 22, Welsh et al disclose the analysis of both gram-positive bacteria (streptococci and staphylococci; see, e.g., p. 7213) and a plant "derived from the class of Monocotyledonae" (rice; see, e.g., p. 7213).

Regarding the rejection of claims 1-4 and 10-11 under 35 U.S.C. 102(b) as being clearly anticipated by Welsh et al in the Office action of May 22, 2002, the Reply traverses the rejection on the following grounds. Applicant argues that Welsh et al "describes a method which was still being developed and points out the limitations of their method (i.e., the inability to distinguish different strains within one species)," whereas Applicant's invention "allows one to distinguish between separate strains within one species." The Reply further argues that Applicant's method is very sensitive and "does not require further extensive experimentation to establish conditions which would allow a differentiation between different species as required for the method designated as AP-PCR by Welsh et al."

Applicant's arguments have been thoroughly considered but are not persuasive. While the response argues that Applicant's invention allows differentiation between, e.g., strains and species, the method that is claimed merely requires the performance of "DNA-fingerprint analysis" that results in "determining the degree of genetic relatedness." The claims do not include any requirement that, e.g, different strains of a species be differentiated from one another, and Welsh et al clearly disclose a method that meets the requirements of the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Accordingly, Applicant's arguments are not persuasive.

Claim Rejections - 35 USC § 103

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (Journal of Genetics & Breeding 50:249-261 [9/1996]) in view of Newton (PCR Essential Data, John Wiley & Sons, 1995, p. 104-107).

Rohde teaches a method of DNA fingerprinting analysis termed inverse sequence-tagged repeat (ISTR) analysis (p. 250). In ISTR analysis, primers "derived from coconut *copia*-like sequences amplify homo- and polymorphic DNA segments in the analysis of plant, animal and human genomes" (p. 250). Rohde discloses steps of isolating DNA, subjecting isolated DNA to PCR amplification, separation of PCR products on gels, and analysis of data to compare genotypes (see p. 250). However, Rohde does not teach Southern blotting of such PCR products and/or transfer of products to a membrane followed by hybridization with a probe. Regarding "Membrane detection of PCR products", Newton teaches that "Immobilization of DNA on to a solid support followed by hybridization to at least one internal probe enhances the sensitivity and characterization of specific product detection compared to gel electrophoresis" (p. 104-5). Accordingly, in view of the teachings of Newton, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rohde so as to have included a step of Southern blotting and hybridization of amplification products with a labeled probe. An ordinary artisan would have been motivated to have made such a

modification for the advantage of enhanced sensitivity of detection, as suggested by Newton.

Regarding the rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Rohde in view of Newton in the Office action of May 22, 2002, the Reply traverses the rejection on the grounds that Rohde is not prior art, for the same reasons discussed in paragraph 4, above. Accordingly, the response to those arguments applies equally herein.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde in view of Newton, as applied to claim 5, above, and further in view of Bell et al (US Patent No. 5,541,060 [6/1996]).

The combined references of Rohde and Newton suggest the use of an internal probe in detection of PCR products immobilized on a solid support, and the references therefore do not teach a method in which "the probe is the primer or the primer pair" employed in amplification, as recited in claim 6. Bell et al disclose the use of a labeled amplification primer in detection of amplification products that have been separated on a polyacrylamide sequencing gel and blotted to a membrane (see Table 1). In view of the teachings of Bell et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rohde in view of Newton so as to have substituted a labeled amplification primer, as taught by Bell et al, for the internal probe disclosed by Newton. It would have been obvious to one of ordinary skill in the art at the time the invention was made that this modification would allow one to detect amplification products in a more sensitive manner

while obviating the need to prepare the separate, internal probe disclosed by Newton. Accordingly, an ordinary artisan would have been motivated to have made such a modification for the advantages of increased efficiency and convenience in detecting amplification products.

Regarding the rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Rohde in view of Newton and Bell et al in the Office action of May 22, 2002, the Reply traverses the rejection on the grounds that Rohde is not prior art, for the same reasons discussed in paragraph 4, above. Accordingly, the response to those arguments applies equally herein.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde in view of Newton (PCR Essential Data, John Wiley & Sons, 1995, p. 49-55 and 155)("Newton-2").

Rohde teaches a method of DNA fingerprinting analysis termed inverse sequence-tagged repeat (ISTR) analysis (p. 250). In ISTR analysis, primers "derived from coconut *copia*-like sequences amplify homo- and polymorphic DNA segments in the analysis of plant, animal and human genomes" (p. 250). Rohde discloses steps of isolating DNA, subjecting isolated DNA to PCR amplification with their primers, separation of PCR products on gels, and analysis of data to compare genotypes (see p. 250). While Rohde discloses the use of radiolabeled primers, the radiolabel taught by Rohde is ^{33}P, rather than ^{32}P, as set forth in the claim. Newton-2 discloses that both ^{33}P and ^{32}P are commonly used in the labeling of PCR primers, and teaches that ^{32}P is typically employed in labeling of PCR amplimers and amplicons, while ^{33}P is typically employed in sequencing

(see in particular pages 54 and Table 4 on page 155). In view of the teachings of Newton-2, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Rohde so as to have labeled the primers employed therein with ^{32}P rather than ^{33}P. As ^{32}P is generally more widely and readily available to practitioners than ^{33}P, and as Newton-2 teaches that ^{32}P may be employed successfully in primer labeling and is generally preferred for the labeling of amplimers and amplicons, an ordinary artisan would have been motivated to have employed ^{32}P in lieu of ^{33}P whenever ^{32}P was more readily available, for the advantage of convenience.

9. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Welsh et al (Nucleic Acids Res. 18(24):7213-7218 [12/1990]).

Welsh et al disclose a method of DNA fingerprint analysis in which genomic DNA is PCR amplified using arbitrary primers (see entire reference). It is a property of the arbitrary primers of Welsh et al that they would hybridize to the DNA sequences of the claims under sufficiently permissive conditions. Welsh et al discloses steps of isolating DNA (p. 7213), subjecting isolated DNA to PCR amplification (p. 7214), separation of PCR products on gels (Figures 2-5), and analysis of data to compare genotypes (see p. 7215-7218). While Welsh et al do not disclose the fingerprinting of DNA sequences meeting the requirements of claim 19-21 using the particular steps set forth above, Welsh et al disclose that their method "can be applied to any species for which DNA can be prepared" (p. 7213). Welsh et al further state that "we have generated discrete fingerprints from genomes 50,000 to 3,000,000,000 base pairs in size, including the

genomes of viruses, humans, and plants (including the rice results shown)," that "We believe a characteristic pattern could be obtained for any genome" (p. 7218). and that "The method would be useful in breeding programs, genetic mapping, population genetics, or epidemiology." Accordingly, in view of the teachings of Welsh et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Welsh et al so as to have practiced the method on "any species for which DNA can be prepared," including those encompassed by claims 19-21, as suggested by Welsh et al. An ordinary artisan would have been motivated to have made such a modification for the advantage of obtaining fingerprints for any of said species for use in "breeding programs, genetic mapping, population genetics, or epidemiology," as taught by Welsh et al.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Welsh et al in view of Newton.

Welsh et al disclose a method of DNA fingerprint analysis in which genomic DNA is PCR amplified using arbitrary primers (see entire reference). It is a property of the arbitrary primers of Welsh et al that they would hybridize to the DNA sequences of the claims under sufficiently permissive conditions. Welsh et al discloses steps of isolating DNA (p. 7213), subjecting isolated DNA to PCR amplification (p. 7214), separation of PCR products on gels (Figures 2-5), and analysis of data to compare genotypes (see p. 7215-7218). However, Welsh et al do not teach Southern blotting of such PCR products and/or transfer of products to a membrane followed by hybridization with a probe. Regarding

"Membrane detection of PCR products", Newton teaches that "Immobilization of DNA on to a solid support followed by hybridization to at least one internal probe enhances the sensitivity and characterization of specific product detection compared to gel electrophoresis" (p. 104-5). Accordingly, in view of the teachings of Newton, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Welsh et al so as to have included a step of Southern blotting and hybridization of amplification products with a labeled probe. An ordinary artisan would have been motivated to have made such a modification for the advantage of enhanced sensitivity of detection, as suggested by Newton.

Regarding the rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Welsh et al in view of Newton in the Office action of May 22, 2002, the Reply traverses the rejection in part on the same grounds discussed in paragraph 5, above. Accordingly, the response to those arguments applies equally herein. The response further argues that Applicant's invention is a "universal method for DNA fingerprint analysis of species selected from all of the different animal kingdoms and genuses," while the method of Welsh et al does not disclose appropriate conditions for the broad use of AP-PCR, necessitating additional experimentation to identify such conditions. These arguments have also been considered but are not persuasive. First, the instant claims do not recite any particular conditions, and are therefore of sufficient breadth to encompass a wide variety of reaction conditions. It is again noted that although the claims are interpreted in light of the specification, limitations from the

specification (e.g., particular reaction conditions that might be employed when practicing a method) are not read into the claims. Further, the specification does not exemplify the use of nucleic acids from the large majority of species encompassed by the claims, nor does the specification indicate that, e.g., a particular, single set of conditions are applicable to any sample type. Accordingly, one of ordinary skill in the art would expect that (as is the case with the method of Welsh et al) the practice of the claimed invention would also require, e.g., routine experimentation aimed at optimizing conditions for fingerprinting a particular set of species. Applicant's arguments are not persuasive.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Welsh et al in view of Newton, as applied to claim 5, above, and further in view of Bell et al.

The combined references of Welsh et al and Newton suggest the use of an internal probe in detection of PCR products immobilized on a solid support, and the references therefore do not teach a method in which "the probe is the primer or the primer pair" employed in amplification, as recited in claim 6. Bell et al disclose the use of a labeled amplification primer in detection of amplification products that have been separated on a polyacrylamide sequencing gel and blotted to a membrane (see Table 1). In view of the teachings of Bell et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Welsh et al in view of Newton so as to have substituted a labeled amplification primer, as taught by Bell

et al, for the internal probe disclosed by Newton. It would have been obvious to one of ordinary skill in the art at the time the invention was made that this modification would allow one to detect amplification products in a more sensitive manner while obviating the need to prepare the separate, internal probe disclosed by Newton. Accordingly, an ordinary artisan would have been motivated to have made such a modification for the advantages of increased efficiency and convenience in detecting amplification products.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone

number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
September 10, 2003

CARLA J. MYERS
PRIMARY EXAMINER